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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,420	08/15/2006	Tsukao Yokoyama	YPO1.001APC	9866

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EXAMINER	
GRUN, JAMES LESLIE	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
03/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,420	YOKOYAMA ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/30/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 30 December 2008 is acknowledged and has been entered. Claims 21-31 are newly added. Claims 1-17 have been cancelled. Claims 18-31 remain in the case.

Applicant's showing of the current ready commercial availability of the "NC1" antibody is sufficient to overcome the deposit requirement made in the prior Office action. Applicant is cautioned that the material required for practice of the method may cease to be known and readily available to the public at some future time. Public access during the term of a patent may affect the enforceability of that patent.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 25 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Johansson et al. (J. Biol. Chem. 267: 24533, 1992) teach populations of noncollagenous domains of collagen (NC1) in glomerular basement membranes. One would expect antibodies

specific for NC1 to bind to NC1 in the glomerular basement membranes of kidney samples (see e.g. Figs. 1-4) regardless of whether the subject providing the sample suffered from nephritis or not. Absent further description and guidance from applicant, one would have no assurance of practicing the method as claimed because one would not be able to discern anything regarding nephritis in the patient merely by detecting binding of an antibody to an antigen known or expected to be present in samples from all patients.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 20, the acronym "GBM" should not be used until fully defined at its first occurrence.

In claim 28, the acronym "AB" is not clear and should not be used until fully defined at its first occurrence.

Applicant's arguments filed 30 December 2008 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 23-27, 30, and 31 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Yokoyama et al. (Cell 35: 40, 2003) in light of the translation made of record.

Yokoyama et al. teach enzyme-linked immunosorbent immunoassays for the detection of circulating noncollagenous domain of collagen (NC1) antigen and antibodies specific for NC1 antigen in biological samples from patients with and without nephritis. Antigen and antibody detection is taught for the determination of early stage glomerulonephritis or a risk therefor. Levels of antigen and antibody were determined in both serum and urine samples. Urine samples are considered herein as a sample derived from kidney. The reference also teaches that an improvement of dialysis therapy would involve the removal of NC1 antigen and antibodies specific for NC1 antigen from the glomerulonephritis patient during dialysis (see e.g. translation pages 7 and 8).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject

matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 21-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yokoyama et al. (Cell 35: 40, 2003), if necessary further in view of Campbell, Cosmo Bio Co. Ltd. catalog and letter, Sugihara et al. (J. Pathol. 178: 352, 1996), and Johansson et al. (J. Biol. Chem. 267: 24533, 1992).

The teachings of Yokoyama et al. are as set forth above and differ from the invention as instantly claimed in not teaching other than enzyme labels in their immunoassays and in not specifically teaching monoclonal anti-NC1 antibodies in their NC1 assay. It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have substituted any known or available notoriously old and well known conventional label in the assay with a reasonable expectation that the conventional label would perform its expected function of labeling for detection in the immunoassays. It would have been obvious to have generated and used monoclonal antibodies in Yokoyama et al. in order to provide a potentially unlimited source of homogeneous reagent for use.

Alternatively, if necessary:

Campbell teaches the general procedure for the production of monoclonal antibodies (pages 3-6) and that substituting a monoclonal antibody for a polyclonal antibody in an established immunoassay "is not novel and is obvious" (page 45).

The Cosmo Bio Co. Ltd. references teach the commercial availability of the K35MONO anti-NC1 monoclonal antibody.

Sugihara et al. teach anti-NC1 autoantibodies in the blood of patients with Goodpasture's syndrome, an anti-glomerular basement membrane antibody-induced glomerulonephritis autoimmune disease. The reference teaches at least one anti-NC1 monoclonal antibody.

Johansson et al. provided monoclonal and polyclonal antibodies to bovine glomerular basement membrane NC1 and used the antibodies in ELISA, Western blotting reactions, and in affinity columns for purification of NC1.

If necessary, it would have been further obvious to one of ordinary skill in the art at the time the instant invention was made to have substituted monoclonal antibodies in the NC1 detection assay of Yokoyama et al. because anti-NC1 monoclonal antibodies were well known to the art as taught, for example, in Cosmo Bio Co. Ltd., Sugihara et al., and Johansson et al., and to substitute monoclonal antibodies is conventional in the art as taught by Campbell. One would have had obvious motivation to have substituted monoclonal antibodies in Yokoyama et al., as modified, in order to provide a potentially unlimited source of homogeneous reagent for use.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claims 18-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yokoyama et al. (Cell 35: 40, 2003) together with Oftshun et al. (US 5871649) and Sugihara et al. (J. Pathol. 178: 352, 1996).

The teachings of Yokoyama et al. are as set forth above and differ from the invention as instantly claimed in not teaching a specific apparatus for use in dialysis removal of NC1 antigen and anti-NC1 antibodies.

Oftshun et al. teach an affinity membrane device in a columnar shape for the removal of deleterious solutes such as autoantibodies in the blood of Goodpasture's syndrome patients (see e.g. col. 19).

Sugihara et al. teach anti-NC1 autoantibodies in the blood of patients with Goodpasture's syndrome, an anti-glomerular basement membrane antibody-induced glomerulonephritis autoimmune disease.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used a device or a series of devices such as those taught in Oftshun et al. for the removal of NC1 antigen and anti-NC1 antibodies during dialysis as desired by Yokoyama et al. because Oftshun et al. teach their device for removal of deleterious solutes, such as autoantibodies, in the blood of patients, such as those having Goodpasture's syndrome, during dialysis and Sugihara et al. teach that anti-NC1 autoantibodies are pathologically found in the blood of patients with an anti-glomerular basement membrane antibody-induced glomerulonephritis disease such as Goodpasture's syndrome. One would have been motivated to remove both the anti-NC1 autoantibodies and NC1 antigen during dialysis, particularly of Goodpasture's syndrome patients, in view of the direct suggestion in Yokoyama et al. to do so and would have expected the device of Oftshun et al., containing the appropriate immobilized ligands, to perform the expected function of affinity removal.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments filed 30 December 2008 with respect to the claims have been fully considered but are moot in view of the new ground(s) of rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ninomiya et al. (J. Cell Biol. 130: 1219, 1995) teach monoclonal antibodies specific for NC1 peptides and their use in various immunoassays.

Borza et al. (J. Biol. Chem. 276: 28532, 2001) elicited monoclonal antibodies to bovine glomerular basement membrane that bound to NC1 in ELISA and were also used in Western blotting reactions. The antibodies were used in affinity columns for purification of NC1 and were used in immunoprecipitation assays with protein G-sepharose.

Yokoyama et al. (Cell 34: 36, 2002) teach induction of glomerulonephritis by injection of the NC1 domain of type IV collagen. The submitted translation is incomplete, however, and it is not clear if immunofluorescent immunohistochemical assays were used to detect glomerulonephritis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
March 17, 2009

/Ann Y. Lam/
Primary Examiner, Art Unit 1641
March 13, 2009